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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/692,364	10/22/2003	Aaron H. Shovers	S006-P03038US	9385

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EXAMINER	
SCHLIENTZ, LEAH H	

ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
10/02/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/692,364	SHOVERS ET AL.	
	Examiner	Art Unit	
	Leah Schlientz	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 August 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,8,9,13-15 and 24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,8,9,13-15 and 24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/2/2007 has been entered.

Status of Claims

Claims 1 and 24 have been amended. Claims 3 – 7, 10 – 12, 16 – 23, 25 and 26 have been cancelled. Claims 1, 2, 8, 9, 13 – 15 and 24 are pending and are examined herein on the merits for patentability.

Response to Arguments

Applicant's arguments filed 8/2/2007, with respect to the rejection of claims 1 – 9, 11 – 18, 20 – 24 and 26 under 35 USC 113, first paragraph, for failing to comply with the written description requirement, have been fully considered but they are not persuasive for reasons set forth hereinbelow.

Applicant's arguments filed 8/2/2007, with respect to the rejection of claims 1 – 9, 11 – 18, 20 – 24 and 26 under 35 USC 113, first paragraph, for failing to comply with the written description requirement (new matter), have been fully considered. The rejection has been withdrawn as being overcome by amendment.

Applicant's arguments filed 8/2/2007, with respect to the rejection of claims 1 – 9, 11 – 18, 20 – 24 and 26 under 35 USC 113, second paragraph, as being indefinite as containing improper Markush terminology, have been fully considered. The rejection has been withdrawn as being overcome by amendment.

Applicant's arguments filed 8/2/2007, with respect to the rejection of claims 1, 2, 8, 9, 13 – 15 and 24 under 35 USC 102(b) and (e) have been fully considered. The rejections have been withdrawn as being overcome by amendment.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2,8, 9, 11 - 18, 20 - 24, and 26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to

reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The invention is drawn to a method of monitoring a selected condition of an animal using a selected monitoring material, the animal having a visually observable nail tissue, comprising selecting a method of introducing the monitoring material into the animal, selecting at least one site under the nail tissue for introducing the monitoring material, introducing the material at the selected sites, monitoring the visually ascertainable indication, observing the visually ascertainable indication to thereby visually ascertain the status of the condition, wherein the visually ascertainable indication is a reversible change in the color of the monitoring material.

The specification fails to provide the requisite description to practice the very broad and generic monitoring method. There are an almost unlimited number of "conditions" of an animal body, and the specification discloses a wide variety of extremely diverse conditions to include immunity, the ability to produce antibodies, the general condition of an animal, hormone levels, temperature, exposure to radiation, lack of sleep, mental stress, the presence of certain levels of proteins, microbes, toxins, etc. (paragraph 22 – 25). The monitoring material may also include a very diverse number of materials. There are an almost unlimited number of species which may represent such a monitoring material (i.e. a multitude of species may be represented by organisms, viruses, bacteria, organic/inorganic materials, etc.) (paragraph 26). There is no description provided regarding which specific monitoring materials is to be selected out of a very large and diverse number of potential materials which is used to monitor

which specific condition out of a very large and diverse number of potential conditions. There are no chemical or biological structures or identities provided to represent any specific monitoring material. Because the structures and physical identities of these elements are undefined, it is unclear how Applicant envisaged any specific combination of which material would be capable of achieving a monitoring function of which specific condition.

Because of the inherent unpredictability of *in vivo* methods, it is essential that a certain degree of guidance is provided to specify what materials are used to monitor what conditions. For example, it is unclear which type of "selected monitoring material" is to be introduced to at least one site under the nail tissue, in order to monitor which of any of an almost unlimited number of "selected conditions." Which type of "organic material" should be selected to monitor lack of sleep, for example; which type of "inorganic material" should be selected to monitor mental stress when introduced under the nail tissue of an animal? Furthermore, the specification does not describe any embodiments of any specific combination of monitoring material and condition to be monitored to show that describe a process for actually practicing the broadly claimed monitoring method. There are no working examples to demonstrate that the invention as claimed may be successfully reduced to practice. Because of the wide variety of chemical or biological moieties which may represent monitoring materials and the wide variety of conditions which may be monitored, a more detailed description of what is being claimed is necessary to show possession of the invention. For example, a *specific material* that can be used to monitor a *specific condition* should be described,

as well as how the monitoring takes place. In sum, the specification does not provide any description of the specifics of the steps required to practice the very broad and generic monitoring method as claimed.

Applicant argues on page 2 of the Response that "conditions to be monitored are discussed in paragraphs 22-25 and 45. Monitoring materials are discussed in paragraphs 26,28, 44." Applicant contends that "even an ordinary physician, after selecting a condition to monitor, could select from known materials to use for monitoring. The specification need not identify every condition and every material, since these things are merely peripheral to the invention, and the specification provides sufficient guidance for one of ordinary skill in the art to selected conditions and materials."

This is non-persuasive because the condition and material to be used in the practice of the method are not merely peripheral to the invention, but are critical features. A variety of widely varying conditions are identified in paragraphs 22-25 and 45 (i.e. lack of sleep, exposure to radiation, presence of toxin or drug, temperature, arthritis, etc.), however, the specification does not identify even a single specific "organic material," for example, to represent a monitoring material, much less one that is capable of reversible color change in response to the status of a "condition". Accordingly, there is nothing of record to demonstrate that Applicant had possession of the claimed method with any reasonable specificity, or any evidence to support that the invention as claimed can be successfully reduced to practice. The complex nature of

physiological conditions should be recognized that such that there is at least some physical and/or chemical basis for the combined selection of condition and material which is capable of reversible color change that in response to the status of the condition.

New Grounds for Rejection

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 24 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The terms "small amount" or "small change" are relative terms which renders the claim indefinite. The terms are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the

> applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 8, 9 and 13 – 15 are rejected under 35 U.S.C. 102(e) as being anticipated by Legge *et al.* (US 7,238,533).

Legge discloses a personal illicit drug detector to be disposed on one or more fingernails. The drug detector includes a layer having a substance chemically reactive to a suspected drug positioned on at least one fingernail of the user, including under the fingernail (column 3, lines 30 – 47). The user can discretely moisten the drug detector on the fingernail with a drink, and color change can be discretely observed (column 3, lines 48 – 55). The composition may include 3-mercaptopropyltrimethoxysilane, for example. The observable color change is interpreted to be reversible to the extent that the indicator does not create a permanent marking on the individual. Regarding claim 15, the order in which the steps are performed does not constitute a functional limitation of the claimed invention over those evidenced by Legge.

Claims 1, 2, 8, 9, 13 – 15 and 24 are rejected under 35 U.S.C. 102(e) as being anticipated by Ribi *et al.* (US 2003/0226978).

Ribi discloses compositions and methods for detection and use of ultraviolet or light radiation using a variety of photochromic agents that can be either reversible or irreversible depending on the intended application. Of particular interest include personal care items, including nail products (paragraph 0013). Various formulations may be prepared which provide adherent coatings to a body surface, such as the skin,

fingernails, etc. For example, a thin layer of fingernail polish may be coated on one or more fingernails so that upon exposure to UV radiation, fingernails will turn colored (paragraph 0030). It is interpreted that the application of such a polish would inherently include application to tissue under the nail to at least some degree, such as the nail bed or cuticle tissue, for example. The photochromic agents are diynes (paragraph 0034). See also example 2 for a nail polish sun sensor. Upon drying, the sensor is exposed to sunlight. A light blue color begins to appear upon mild sun exposure. A deep dark blue color appears upon prolonged exposure. Regarding claim 15, the order in which the steps are performed does not constitute a functional limitation of the claimed invention over those evidenced by Ribi.

Conclusion

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leah Schlientz whose telephone number is 571-272-9928. The examiner can normally be reached on Monday - Friday 8 AM - 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LHS

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER